

REMARKS

This is a full and timely response to the non-final Official Action mailed **January 12, 2009**. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

Claims 22-53 and 63-79 were withdrawn from consideration under the imposition of a previous Restriction Requirement and cancelled without prejudice or disclaimer.

Subsequently, claims 2, 6, 55, 59, 61 and 99 were also cancelled without prejudice or disclaimer

By the forgoing amendment, claim 64 has been amended. New claim 100 has been added. Thus, claims 1, 3-5, 7-21, 54, 56-58, 60, 62, 80-98 and 100 are currently pending for further action.

35 U.S.C. §112, first paragraph:

The sole issue raised in the current Office Action is a rejection of claims 1, 3-21, 54, 56-60, 62 and 80-98 under 35 U.S.C. § 112, first paragraph. According to the Action, these claims fail to satisfy the written description requirement of § 112, first paragraph.

In independent claims 1, and 54, the applicants claim using the same inkjet dispenser to dispense the structural material and the jettable pharmaceutical solution. However, support for this limitation is not provided in the specification. The specification (see paragraph 0019, 0021, 0022, 0040 and Figures 1 and 4-5) teaches using a plurality of ink jet dispensers (150, 150') to dispense the structural material and jettable pharmaceutical solution.  
(Action, p. 2).

In response, Applicant notes that claim 54 does *not* recite that the structural material is dispensed with an inkjet dispenser. Consequently, the position taken in the Office Action as

to claim 54 is entirely incorrect. For at least this reason, the rejection of claim 54 and its dependent claims under 35 U.S.C. § 112, first paragraph, is clearly in error and should be reconsidered and withdrawn.

With respect to the rejection of claim 1, which does recite that the structural material is dispensed with an inkjet dispenser, Applicant refers to Applicant's specification at paragraph 0039 which states that "the polymer/gelatin solution (400) may be disposed onto a substrate (180) by an inkjet material dispenser (150)." (Applicant's specification, paragraph 0039). Subsequently, the specification states "the jettable pharmaceutical solution may be jetted from the inkjet material dispenser (150)." (Applicant's specification, paragraph 0043).

Thus, Applicant's specification contains a clear written description in which both the structural material and the pharmaceutical solution are dispensed from the "inkjet material dispenser (150)." This provides sufficient written description to support the aspect of claim 1 at issue in the rejection under § 112, first paragraph.

Moreover, Applicant respectfully notes that the Office Action is imposing an unnecessarily narrow definition of the term "ink jet dispenser" in construing Applicant's claims. Applicant notes that, in most all inkjet dispensing systems, different nozzles or even separate print heads are provided to dispense different materials, such as differently colored inks. These systems are still referred to in the art as "ink jet dispensers."

Consequently, the "ink jet dispenser" recited in claim 1 may refer to the carriage (140) and the two inkjet heads (150, 150') collectively as an "inkjet dispenser." Such a construction would be supported by Applicant's specification at paragraph 0020. Paragraph 0020 reads as follows. "The computing device (110) that is controllably coupled to the servo mechanism (120), as shown in Figure 1, controls the selective deposition of both a structural material used to form the edible structure (170) as well as a jettable pharmaceutical solution

(160).” (Applicant’s specification, paragraph 0020). Thus, the inkjet dispensing system comprising the computing device (110), servo mechanism (120) and the carriage (140) and the two inkjet heads (150, 150’) comprise a single inkjet dispensing unit that provides for “the selective deposition of both a structural material used to form the edible structure (170) as well as a jettable pharmaceutical solution (160).” (*Id.*).

There is no basis for construing claims 1 and 54 so narrowly as to require that both the structural material and the pharmaceutical solution are dispensed through exactly the same nozzles of an inkjet dispenser. To the extent that the rejection under § 112, first paragraph, is based on such a narrow construction of the claim language, Applicant respectfully rejects any such limiting construction of the claims.

Prior Art:

Although not at issue in the present Office Action, Applicant’s claims were previously rejected under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of U.S. Patent App. Pub. No. 2003/0059471 to Compton et al. (“Compton”) and U.S. Patent App. Pub. No. 2002/0197388 to Brown et al. (“Brown”). In response, Applicant notes that Compton teaches a composition that includes “a plurality of discrete, substantially flat flakes...wherein the flakes comprise a drug or a nondrug nonnutritional active agent.” (Compton, paragraph 0012). Compton further teaches that “in some cases, inert materials (e.g. gels, absorbents, etc.) may be used to create a flake” wherein the fabrication process includes “[i]nkjet[ting]...slurry onto belt dryer or barrel or flat surface drying device,” drying the slurry by heat or vacuum, and/or polymerizing the flakes by radiation. (*Id.*, paragraphs 0331 to 0335). Compton further teaches that “[t]he flake may then be placed in contact with

a drug so that [the drug] is absorbed. A subsequent drying or other step (e.g. polymerization) may be necessary to complete the formation of the flake.” (Id.).

Applicant notes that these teachings from Compton are clearly different than the claimed method in which a single inkjet dispensing unit, whether comprised of two or more inkjet heads or dispensing units, is used to dispense both structural material and pharmaceutical solution. The Examiner previously agreed that “Compton et al. fails to teach using the same inkjet used to dispense the structural material [and] to dispense the pharmaceutical solution as required by claim 1.” (Action of July 1, 2008, p. 3).

As a result, that Office Action attempted to demonstrate *prima facie* obviousness by citing to Brown’s teaching that an “an ink jet head is used to apply [active] coating material to the substrate.” (Id., Brown, paragraphs 0040-0041). However, Brown does not teach or suggest here or elsewhere the concept of using the same inkjet dispenser to dispense both “a structural material” and “a jettable pharmaceutical solution onto said cured structural material” as recited by claim 1.

By using the same inkjet dispensing unit to dispense both structural material and the pharmaceutical solution onto the structural material, the efficiency of the claimed step of “dispensing alternating layers of said structural material and said pharmaceutical solution” is increased. Thus, dispensing the structural material and the jettable pharmaceutical solution using the same inkjet dispenser provides a significant advantage that cannot be ignored.

Moreover, both Compton and Brown utterly fail to teach or suggest the claimed step of “dispensing alternating layers of said structural material and said pharmaceutical solution.” (claim 1).

Under the analysis required by *Graham v. John Deere*, 383 U.S. 1 (1966) to support a rejection under § 103, the scope and content of the prior art must first be determined,

followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Compton and Brown, did not include the claimed subject matter, particularly the steps of “with said inkjet dispenser, dispensing a jettable pharmaceutical solution onto said cured structural material” and “dispensing alternating layer of said structural material and said pharmaceutical solution.” (claim 1, emphasis added).

The differences between the cited prior art and the claimed subject matter are significant because the claimed subject matter “produce[s] a layered solid oral dosage form of a pharmaceutical without the traditionally complex and costly manufacturing process” and is “precisely formed using inkjet technology.” (Applicant’s specification, paragraph 0025). Thus, the claimed subject matter provides feature and advantages not known or available in the cited prior art. Consequently, Compton and Brown do not support a rejection of Applicant’s claims under 35 U.S.C. § 103 and *Graham*.

New Claim:

The newly added claim is thought to be patentable over the prior art of record for at least the same reasons given above with respect to the original independent claims. Therefore, examination and allowance of the newly added claim is respectfully requested.

Conclusion:

In view of the following arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicants reserve the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of

the dependent claims not explicitly addressed herein, in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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